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PATENT- OG VAREMÆRKESTYRELSEN

TITLE

A wound care device

FIELD OF THE INVENTION

This invention relates to wound care devices comprising an active pain-relieving agent for local pain relief in an open wound setting and a method of treating pain in such wounds.

BACKGROUND OF THE INVENTION

It is widely recognised that wound pain is one of the major problems associated with wounds or ulcers. Wounds are by definition divided into two categories: Acute and chronic wounds. Acute wounds may be wounds such as burns and surgical wounds, while chronic wounds may be in the form of pressure sores, leg ulcers and diabetic ulcers. Pain can be associated with both chronic and acute wounds although the influence on patient's well-being will be more pronounced when the wound is chronic.

Pain can be divided into three categories: Acute pain, non-malignant pain and cancer pain. Wound pain will often be either acute or non-malignant dependent on the character of the actual wound and whether the wound is being manipulated or not e.g. during a dressing change. Furthermore, the pain will in general have nociceptive or neurogen origin.

The actual kind of wound pain can be divided into three classes:

- Non-cyclic acute wound pain, which may occur during for instance at debridement of necrotic tissue in a wound or removal of drainage.
- Cyclic acute wound pain, which may occur during for instance dressing changes or in some cases debridement.
- Chronic wound pain, which is a persistent pain that occur even without manipulation of the involved skin or tissue, i.e. pain between dressing changes.

In the following we will primarily address relief of the persistent pain or the chronic pain associated with wounds between dressing changes. However,

treatments suitable for this purpose may also be able to relieve pain during dressing change and debridement as described below.

Pain in itself is of course a major discomfort for the patient and will therefore affect patient's quality of life. In addition, pain stimulates catecholamine release and as a result of that local vasoconstriction arises and a reduced oxygen supply to a cutaneous wound will occur. This may affect wound healing and resistance to infection of the wound. Furthermore, wound healing may also be delayed due to the general influence pain may have on the patient, such as loss of appetite, less mobility, worse overall condition and lack of enthusiasm. However, the possible effect of pain on wound healing has not been proven in the literature and is therefore speculative. In contrast, it is well recognized that pain has an impact on the health related quality of life (HRQoL) for patients.

Wound pain has proven to be decreased by modern moist wound healing principles. Moist wound healing dressings keep the environment under the dressing moist but are at the same time capable of absorbing considerable amounts of exudate from the wound, in order to protect the periulcer skin and to avoid leakage. During the wear time of a moist wound healing dressing, tissue and nerve endings remain moist. Such dressings, e.g. hydrocolloid dressings will be soothing and less painful than traditional dry gauze dressings during application and in situ. Debridement will often also be less painful as the wound bed will be kept in a moist condition and thus no painful drying out is seen.

Although moist wound healing has been proven to improve healing rates, relieve pain in situ, prevent the wound bed from drying out, decrease the discomfort with wound debridement and overall improve the quality of life for the patient, added benefits in terms off a more direct way of addressing the local wound pain between dressing changes associated with wounds are still needed.

It is well known in the art to incorporate analgesics or anaesthetics into topical products for treatment of pain or to produce anaesthesia in intact skin surfaces or systemically in the body. These products may be in the form of trans-dermal dressings or patches, creams, gels or ointments. In order to enhance the rate at

which the drug passes through the skin to reach the systemic circulation from e.g. the trans-dermal patch or to achieve an appropriate formulation for intact skin surfaces it is often desirable or even necessary to incorporate other components. These components will interfere with an open wound setting in terms of producing possible irritation, sensibilisation or even toxicological effects in the open wound setting and to the often very fragile perulcer skin around the open wound.

In International Patent Application No. WO 94/23713 is disclosed a trans-dermal anti-inflammatory composition. The compositions may be used for topical and trans-dermal application, such as ointments and dressings and the anti-inflammatory composition is preferably NSAIDs (non-steroid anti-inflammatory drugs).

However, delivering drugs to intact healthy skin and to the systemic circulation is very different from delivering drugs locally to open wounds or damaged skin. The skin provides an effective barrier between the drug and the underlying tissue and blood circulation in trans-dermal delivery, and therefore, the drug has to be formulated in such a way that it is capable of overcoming this barrier. Also the concentration of the drug in the trans-dermal formulation has to be higher in order to overcome the skin barrier and reach the systemic circulation in a plasma concentration high enough for systemic effect. A wound is provided with little or no barrier, and furthermore, the wound will often exudate and may be contaminated. The exudate comprises complex wound components such as enzymes, proteins or other plasma components. The barrier for the release of the drug for local use in an open wound will be the medical device and not the intact skin.

A trans-dermal patch or a topical cream or ointment will not be a part of an open wound handling solution and neither will the adhesive nor the other components of the patch be designed for use on an open woundor for contact with the very fragile skin surroundings. Also the drug concentration in a trans-dermal system or a topical ointment, gel or cream may be too high to be used in an open wound where no absorption barrier is seen. Furthermore, additives such as penetration enhancers comprised in the creams, gels or ointments or trans-dermal patches

will make them unsuitable for use in an open wound, as these additives often are too aggressive or even toxic for introducing directly into an open wound.

Most wound care products are prepared without such additives as these additives may interfere with the wound healing and influence the well being of the patient.

A controlled release of drugs is often desired both in trans-dermal delivery and open wound treatment. However, the release mechanisms may be quite different in the two systems. In a trans-dermal device such as a patch, cream, ointment or gel, the skin barrier may serve as the controlling release layer. The additives may further control the release. In a wound care device, the release may be controlled in other ways, e.g. by the amount of exudate from the wound, or by using controlled release matrices.

Analgesics in a broad term can relieve pain in open wounds without seriously interfering with the sense perception. In contrast, anaesthetics interfere with sense perception when applied locally, and can result in loss of consciousness when used centrally. Loss of sense perception in a wound and surroundings is considered to be irrationally and inconvenient since the patient loose the ability to feel possible injury and change in the wound. Therefore it may be preferred to use analgesics in order to relieve wound pain over a longer period.

In US Patent No. 6,312,713 is disclosed a thin-layered dressing for surface wounds which gradually releases drugs, such as analgesics. The drug is incorporated in a hydrophilic polymeric matrix and may be used topically. The reference is silent with respect to the amount of active agent incorporated therein.

In US Patent No. 6,048,850 is disclosed a method of selectively inhibiting PGHS-2 in a human host. The reference is silent with respect to local wound treatment.

US Patent No. 6,190,689 discloses a trans-dermal device comprising a hot-melt adhesive with an incorporated substance. The use of pain relieving agents in the

treatment of wounds is mentioned, but the reference is silent with respect to any details or examples to this subject.

In International Patent Application No. WO 00/07574 is disclosed medicinal products with retarded pharmacological activity. The products are primarily intended for use in catheters, though use in wound care devices is mentioned.

In EP 808 158 B1 a single-dose pharmaceutical form for delivery of active substances to a wound is described. It is in the form of a film-like flexible substrate. The reference is silent with respect to the use of pain relieving substances.

Thus, there is still a need for a medical device addressing superior wound management as well as local pain relief in terms of addition of analgesic compounds. Such a wound care device is achieved by the present invention combining a flexible use with the pharmacological effects of a pain relieving agent, that supply pain relief locally to a wound and nearby surroundings but not systemically i.e. in the body.

BRIEF DESCRIPTION OF THE INVENTION

The present invention relates to a wound care device for treatment of pain in a wound comprising an active pain relieving composition.

The invention further relates to a method of treating pain at a wound site.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is further described in the drawings wherein Figure 1 shows release profiles of a device of the invention compared to a foam dressing.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a wound care device for local treatment of pain in wounds, said device comprising an active pain relieving composition, said composition is an anti-inflammatory pain killing agent, wherein the amount of pain killing agent in the device is below the systemic or topical daily unit dose for sys-

temic treatment using the agent and wherein said anti-inflammatory pain killing agent is in direct contact with the wound.

The direct contact between the active agent and the wound provides a number of advantages. The amount of active agent may be reduced and the likelihood that a substantial portion of the active agent incorporated actually reaches the wound is improved. Furthermore, the release of the active agent is easier controlled due to the direct contact.

The direct contact may be obtained by providing the active agent on the wound facing surface of the device or by incorporating the agent in a wound contacting layer.

The device may exhibit non-stick properties with regards to the wound. These properties may be obtained by selecting a material with this inherent property or by coating the alternatively selected material with a non-stick agent.

Preferably the device of the invention is in the form of a sheet-like layer. This layer may be prepared from any suitable material, such as a web, a net, a knit, a woven or a non-woven fabric, a permeable or perforated film or a foam, or a hydrogel provided that the material exhibits a suitable permeability for wound exudate.

Most preferably the device of the invention is in the form of an open fabric. The fabric may be coated or impregnated with a composition comprising the active ingredient. In a preferred embodiment of the invention the composition further comprises a non-stick agent, such as petrolatum.

Depending on the amount of wound exudate the sheet-like device may be used alone or in combination with a secondary dressing having wound exudate handling means. By having the ability to combine the sheet-like device with any type of secondary dressing an increased flexibility in the wound treatment is achieved.

The device of the present invention may comprise any material or composition of materials that either dissolves, swells or allows water diffusion upon contact with water or water based solutions. The device may comprise one or more components selected from the group of PVP, PVA, polylactic acids, polysaccharides such as carboxy methyl cellulose, hydroxymethyl cellulose, chitosan, alginate, or polyacrylic acids, methacrylates, silicones, styrene-isoprene-styrene mixtures, vaseline, glycols such as PEG or PEG/PPG mixtures or polyurethane. The material may be hydrophobic or hydrophilic or a combination thereof.

In one embodiment of the invention the device may comprise absorbent material. A limited amount of absorbent material is desired in order to promote moist wound healing without having this as a primary purpose. The absorbent material may be selected from the group of absorbing foams, hydrogels, or pastes, hydrosheets or be in the form of hydrocolloids and/or alginates. The absorbent material may be in the form of a separate element or particulate and homogeneously distributed in the dressing.

Typically, the release of active agents in a wound dressing is dependent of the amount of wound exudates. However, it may be desirable to control the release without being dependant on the amount of wound exudates.

In different healing phases, wounds will produce different amounts of exudate dependent on the type of wound. Wounds with less exudate can also be painful and thus a wound care device designed to address this is needed. If the release is dependent on the amount of exudate, a simple solution will be to increase the amount of pain relieving substance in the device. However, if the wound is highly exudating the need will be the opposite. Further, it is difficult in a clinical situation to evaluate the actual level of exudate when choosing a specific local pain relieving wound care device. Therefore it may be desired to have a release system that is substantially independent of the amount of wound exudate.

In a preferred embodiment of the present invention the release of the pain killing agent is substantially independent of the amount of wound exudates.

It has surprisingly been shown that the release of active agent in the device of the invention may be substantially independent of the amount of wound exudates present, but it is preferred that a certain amount of moisture is present in order to achieve moist wound healing and for initiation of the release process. In the case of a dry wound, a portion of saline water may be added to the wound before application of the device of the invention.

In one embodiment of the invention the amount of pain killing agent is less than 75% of the systemic or topical daily unit dose for systemic treatment using the agent.

In another embodiment of the invention the amount of pain killing agent is less than 50% of the systemic or topical daily unit dose for systemic treatment using the agent.

It may be preferred that the amount of pain killing agent is less than 25% of the systemic or topical daily unit dose for systemic treatment using the agent.

It is even more preferred that the amount of pain killing agent is less than 10% of the systemic or topical daily unit dose for systemic treatment using the agent.

In one embodiment of the invention the amount of pain killing agent is less than 5% of the systemic or topical daily unit dose for systemic treatment using the agent.

By the phrase "systemic or topical daily unit dose for systemic treatment for a pain killing agent" is meant the daily dose for achieving a systemic pain reliving effect, i.e. achieving a desired plasma concentration.

In Table 1 are shown examples of systemic or topical daily unit doses of various pain killing agents. Examples are shown below in the range of normally recommended use for adults:

TABLE 1

Drug	Systemic daily unit dose	Topical daily unit dose
Naproxen	200 – 500 mg	Not available
Ketoprofen	100 – 300 mg	375 mg
Piroxicam	10 – 20 mg	25 mg
Ibuprofen	1200 –2400 mg	500 – 800 mg
Celecoxib	200 – 400 mg	Not available
Acetylsalicylic acid	2 –4 g	Not available
Indomethacin	150 – 200 mg	Not available
Acetaminophen	2 – 4 g	Not available
Diclofenac	150 – 200 mg	Not available

The analgesics in the device of the invention may be released over time locally to the wound. Preferably, the release of the pain relieving composition is so low that no systemic effect is seen. Thus, the concentration of analgesics in the device of the invention may be so low that little or no effective systemic plasma concentration can be found. This will reduce or even eliminate the possible systemic side effects of the analgesics, and at the same time provide the patient with maximum safety, as oral doses or topical doses on intact skin can be taken at the same time. Thus, the device renders it possible to ingest additional medication, if needed, orally or topically of the same type as in the wound care device, without the risk of overdosing. Furthermore, side effects are lowered and compliance will be better as well as the HRQoL.

For different analgesics, the plasma concentration for systemic effect in the lowest range is reported to be as follows given as examples: Acetylsalicylic acid: 270 µg/ml ; Ketoprofen: 3 µg/ml; Ibuprofen: 10 µg/ml; Piroxicam: 1 µg/ml. Thus, a wound care device for treatment of pain in a wound releasing analgesics locally to a wound site may be designed in such a way that the plasma concentration is under the lowest range for systemic effect in the body.

This is also true for other anti-inflammatory pain reliving compositions being suitable for incorporation into medical devices for local treatment of wound pain in open wounds.

It is widely held that anti-inflammatory pain killing agents, such as NSAIDS, are unsuitable for use in open wound settings. The compositions are primarily used for treatment of systemic diseases, not for local treatment. It is further believed that the compositions may cause local irritation, as well as it has been recommended to avoid use of such compositions in open wounds.

It has surprisingly been found that by incorporating an anti-inflammatory pain killing agent in a wound care device, a local pain-relieving effect in an open wound is achieved. Even though the active agent is in direct contact with the wound, no local side effects have been seen and the plasma concentrations, if any, of the agent were below the concentrations for systemic effect.

The device according to the present invention is primarily intended for use as local pain relief. When a systemic effect of the pain-relieving agent is desired e.g. when providing pain relief against rheumatoid arthritis, muscle pain or headaches, orally ingested analgesics may be preferred. The pain relieving composition of the device of the invention may be applied to damaged skin locally and directly onto an open wound without interfering with the wound healing.

Prostaglandins, leukotrienes, and thromboxanes are key inflammatory mediators produced from arachidonic acid. Inhibition of the synthesis of these mediators is the target of the most highly prevalent class of anti-inflammatory drugs, the NSAIDs. Inflammatory mediators will stimulate pain nociceptors and as a result pain is produced.

Pain impulses in skin tissue arise from pain receptors in the skin and deeper structures. The intensity of the pain increases when the number of receptors activated and the frequency of impulses increase. The perception of pain in e.g. peripheral tissue such as the skin begins with stimulation of nerve fibres called nociceptors. In a process called transduction, a nociceptive stimulus makes no-

ciceptor membranes permeable to sodium ions. In a second process known as transmission, the influx of sodium ions sends a signal to the dorsal horn of the spinal cord. In a third process, modulation, systems that inhibit and facilitate pain act on the generated signals. Finally in the perception process a factor called plasticity, which is based in part on prior experienced pain, determines how intensely the pain is perceived. Pain is therefore also subjective. It has both a psychological and physiological component. Acute, and social, cultural and psychological factors affect it. The feeling of pain is protective in situations where it alerts the body of actual or potential damage. Beyond these situations its function is less clear.

Inflammatory pain is believed to be important for the actually feeling of chronic or persistent wound pain. It is believed that tissue injury as e.g. seen in chronic wounds triggers the release of multiple inflammatory mediators that themselves, alter nociceptor function. The level of inflammation is therefore elevated and may be lowered by addition of anti-inflammatory drugs locally to the wound that would lead to pain relief.

Preferably the pain relieving composition comprises an anti-inflammatory painkilling agent that blocks the production of inflammatory mediators produced from arachidonic acid.

More preferably the pain-killing agent is a NSAID (non-steroid anti-inflammatory drug). NSAIDs generally have analgesics and antipyretic properties along with their anti-inflammatory capabilities. Anti-inflammatory pain killing agents interact with enzyme targets such as cyclooxygenase-inhibiting NSAIDs. The enzymes PGHS (prostaglandin H synthease), commonly know as COX (cyclooxygenase), is responsible for processing arachidonic acid into inflammatory mediators. COX comes from two isoforms COX 1 and COX 2. COX 1 is produced in a more or less constant level at all times and is involved in forming the prostaglandins that perform several important functions, including protection of the gastric mucosa and support of renal function. Consequently, inhibitors of COX 1 may interfere with the gastric mucosa and renal function. COX 2, which is inducible, is expressed after tissue injury and promotes inflammation. Thus, selective inhibition

of COX-2, with sparing of COX 1 activity, should be expected to block inflammation without gastric and renal side effects upon oral administration. However, use of COX 1 locally in an open wound setting will not produce any systemic side effects. Classical NSAIDs acts on both COX 1 and COX 2 whereas newer drugs work selectively on COX 2.

Thus, in one embodiment of the invention the pain relieving composition may be capable of inhibiting mediators responsible for processing arachidonic acid into inflammatory mediators.

In preferred embodiment of the invention the pain relieving composition may be capable of inhibiting COX 1 and COX 2.

In one embodiment of the invention the pain relieving composition may be capable of specifically inhibiting COX 2.The pain relieving composition may comprise one or more compounds chosen from the group of anti-inflammatory compositions such as Phenylpropionic acids, Phenelacetic acids, Indoleacetic acids, Pyrroleacetic acids, N-Phenylacetic acids, Salicylates, Enolic acids, Phenols, Non-acids or Coxibs.

Examples of such compounds for the pain relieving composition may be: Propionic acid derivatives such as Naproxen, Ibuprofen, Ketoprofen, Fenoprofen, Flurbiprofen Dexibuprofen or Tiaprofenic acid, Acetic acid derivatives such as Diclofenac, Aiclofenac, Fenclofenac, Etodolac, Aceclofenac, Sulindac or Indomethacin, Pyrroleacetic acids such as Ketorolac or Tolmetin, N-Phenylacetic acids such as Mefenamic acid, Salicylates such as Acetyl salicylic acid (Aspirin), Salicylic acid or Diffunisal, Pyrazolon derivatives such as Phenylbutazone, Oxicam derivatives such as Piroxicam, Tenooxicam, Meloxicam or Lornoxicam, Enolic acid derivatives Aminopyrene or antipyrene, Phenols such as Acetaminophen or Phenacetin, Non-acid derivatives Nabumeton, Coxib derivatives such as Celecoxib or Rofecoxib.

Compounds inhibiting COX 2 specifically may be Coxib derivatives such as Celecoxib or Rofecoxib.

In one embodiment of the invention the pain relieving composition is Ibuprofen.

In another embodiment of the invention the pain relieving composition is Ketoprofen.

The pain relieving composition may be incorporated as particles, coated particles or diluted in constituent phases of the medical device or distributed in an aiding agent therein.

The particles may be mixed with one or more of the constituents of the wound care device, such as the particles may be incorporated into an adhesive, an absorbent layer or they may be incorporated in a film.

The pain relieving composition may be dissolved or suspended in one or more of the constituents of the wound care device or alternatively in one or more constituents acting as precursor material for the constituent.

In one embodiment of the invention the particles may be dissolved in an aiding vehicle in the form of a liquid or solid and may appear as a discrete phase in one or more of the components of the device, e.g. a water insoluble composition may be incorporated into an hydrophobic vehicle or vice versa.

The wound care device may further comprise a controlled release system.

The pain relieving effect of the device according to the invention is over time originated from release of the pain killing agent to the wound. When studying a dressing that has been applied over an open wound for a period, the pain killing agent diminish or disappear in the area directly over the wound due to a release to the wound, while a negligible amount will be released in the area over the periulcer skin.

In one embodiment of the invention the pain relieving component may be in the form of coated particles with controlled release properties. The coating may be

any suitable coating known in the art of release systems providing the particles with the desired release properties. An example may be Ketoprofen particles coated with an Eudragit grade.

Preferably, the device of the invention is in the form of a wound dressing, or a part of a wound dressing, such as a wound contacting layer. The device or part of the device is preferably soft, non-sticking to the wound bed and easily removable.

The dressing may be in the form of a single unit or a layered product and may be used as a primary dressing together with a secondary dressing. A primary dressing is the part that is in direct contact with the wound bed.

The secondary dressing may comprise an absorbent element. It may in itself show adhesive properties or it may not show adhesive properties and it will then typically be secured to the desired site using conventional means such as a cover dressing.

The device of the invention may comprise an adhesive.

The device of the invention may comprise a skin-contacting surface comprising an area showing a skin friendly adhesive.

Such a dressing may suitably be a dressing comprising a substantially water-impervious layer or film and a skin-friendly adhesive in which an absorbing constituent or element is incorporated.

The skin-friendly adhesive may be any skin-friendly adhesive known per se, e.g. an adhesive comprising hydrocolloids or other moisture absorbing constituents such as the adhesives disclosed in US patent No. 4,231,369 and in US patent No. 4,367,732 comprising hydrocolloids. A dressing comprising a separate absorbing element may e.g. be of the type disclosed in US Patent No. 5,051,259 or 5,714,225.

A water impervious layer or film may be of any suitable material known per se for use in the preparation of wound dressings e.g. a foam, a non-woven layer or a polyurethane, polyethylene, polyester or polyamide film. A suitable material for use as a water impervious film is a polyurethane such as the low friction film material is disclosed in US patent No. 5,643,187.

In another embodiment of the invention the device may be a wound cavity filler. The cavity filler may e.g. be in the form of fibres, a sheet, a gel or a hydrogel, foam or powder.

The device of the invention may further comprise one or more active ingredients besides the pain killing agent.

The wound care device according to the invention may comprise one or more active ingredients, e.g. a pharmaceutical medicament. Examples of such pharmaceutical medicaments such as bacteriostatic or bactericidal compounds, e.g. iodine, iodopovidone complexes, chloramine, chlorohexidine, silver salts such as sulphadiazine, silver nitrate, silver acetate, silver lactate, silver sulphate, silver sodium thiosulphate or silver chloride, zinc or salts thereof, metronidazol, sulpha drugs, and penicillin's, tissue-healing enhancing agents, e.g. RGD tripeptides and the like, proteins, amino acids such as taurine, vitamins such ascorbic acid, enzymes for cleansing of wounds, e.g. pepsin, trypsin and the like, proteinase inhibitors or metalloproteinase inhibitors such as illostat or ethylene diamine tetraacetic acid, cytotoxic agents and proliferation inhibitors for use in for example surgical insertion of the product in cancer tissue and/or other therapeutic agents which optionally may be used for topical application, emollients, retinoids or agents having a cooling effect which is also considered an aspect of the invention.

The active ingredient may also comprise odour controlling or odour reducing material such as charcoal.

The invention further relates to a method of treating pain at a wound site compris-

ing applying to the wound a wound care device comprising an active pain relieving composition.

The pain relieving composition may preferably be an anti-inflammatory pain relieving composition, said composition is an anti-inflammatory pain killing agent, wherein the amount of pain killing agent in the device is below the daily unit dose for systemic treatment or daily unit dose for topical treatment using the agent and wherein the pain killing agent is in direct contact with the wound.

When applying a wound care device according to the invention to a wound, the pain relieving composition is brought into direct contact with the wound and will then be released in a controlled manner to the wound bed, whereby pain relief is achieved. Preferably the pain relieving composition will be released over a period of time, in order to provide a controlled or sustained release of the composition. Thus, a prolonged wear time of the dressing is achieved, rendering it possible to avoid frequent dressing changes. Change of dressings is often associated with pain; hence a low frequency of dressing changes is desired.

EXAMPLES

EXAMPLE A

Preparation of a dressing with direct wound contact

200 micron of mixture consisting of:

Ibuprofen	2,5% w/w
carboxymethyl cellulose	15% w/w
Vaseline	82,5% w/w

Mixture was heated to 60°C and mixed with an Ultre Turrax equipment for 10 minutes at 16000 rpm. The mixture was then applied and impregnated onto a simple cotton net.

EXAMPLE B

Preparation of a foam dressing

A polyurethane foam was prepared in the following way:

100 parts w/w Hypol2002 (Dow Chemical Company)

1 part w/w Pluronic 62 (BASF)

100 parts w/w water

1 part w/w Ibuprofen

The materials were mixed together for approximately 15 seconds. The liquid was poured into a mould and allowed to react for 10 minutes. The resulting foam sheet was dried in an oven at 70°C for 30 minutes, and then cut into 20 x 20 cm dressings with a thickness of 4,4 mm. A top film was laminated onto one side of the foam dressing. The device may further be sterilized using gamma radiation.

Method

A diffusion test on Franz diffusion cells was established to investigate in vitro simulation of a high and low exuding ulcer. Condition1 represents a high exuding ulcer, whereas condition 2 represents a low exuding ulcer.

The Franz diffusion cell comprises a donor compartment and a receptor compartment divided by a release unit. The donor compartment was empty and the receptor compartment was filled with a USP phosphate buffer solution (pH 7,4). The release unit was placed on top of the receptor compartment with a water impermeable rubber outer layer on top that leaves the donor compartment dry.

Condition 1:

For measurement on a flow-through cell, the Franz diffusion cell was used. Sample roundels of 20 mm in diameter were applied onto each cell as described above. The cell had an inner volume of 14 ml. The flow rate was 13,1 microLiter/minute. Auto sampling was carried out at different adequate times.

Condition 2

Sample roundels of 20 mm in diameter were applied onto an agar middle layer covering a membrane with a pore size of 0,02 µm. This will diminish the donation of water to the sample. The agar membrane layer was then applied on top of the receptor compartment and the sample was placed on top of this as described above. The results are shown in Figure 1.

The results show clearly that the difference in release measurement i.e. condition type has a large impact on Sample B. In Sample B, the release of the active ingredient is strongly influenced by the amount of exudates, while the release from the dressings of Sample A is only slightly impacted by the exudate.

CLAIMS

1. A wound care device for local treatment of pain in a wound, said device comprising an active pain relieving composition, said composition is an anti-inflammatory pain killing agent, wherein the amount of pain killing agent in the device is below the daily unit dose for systemic treatment or daily unit dose for topical treatment using the agent and wherein said anti-inflammatory pain killing agent is in direct contact with the wound.

2. A device according to claim 1, wherein the device is in the form of a sheet-like layer.

3. A device according to claim 1 or 2, wherein the device comprises one or more components selected from the group of PVP, PVA, polylactic acids, polysaccharides such as carboxy methyl cellulose, hydroxymethyl cellulose, chitosan, alginate, or polyacrylic acids, methacrylates, silicones, styrene-isoprene-styrene mixtures, vaseline, glycols such as PEG or PEG/PPG mixtures or polyurethane.

4. A device according to any of the preceding claims, wherein the release of the pain killing agent is substantially independent of the amount of wound exudate.

5. A device according to any of the preceding claims, wherein the amount of pain killing agent is less than 75% of the daily unit dose for systemic treatment or daily unit dose for topical treatment using the agent.

6. A device according to any of the preceding claims, wherein the amount of pain killing agent is less than 50% of the daily unit dose for systemic treatment or daily unit dose for topical treatment using the agent.

7. A device according to any of the preceding claims, wherein the pain killing agent is a NSAID.

8. A device according to claim 7, wherein the pain killing agent is ibuprofen.

9. A device according to any of claims 1-8 wherein the device further comprises a controlled release system.

10. A method of treating pain at a wound site comprising applying to the wound a wound care device comprising an active pain relieving composition, said composition is an anti-inflammatory pain killing agent, wherein the amount of pain killing agent in the device is below the daily unit dose for systemic treatment or daily unit dose for topical treatment using the agent and wherein the pain killing agent is brought into direct contact with the wound.

ABSTRACT

A wound care device

A wound care device for local treatment of pain in a wound, said device comprising an active pain relieving composition, said composition is an anti-inflammatory pain killing agent, wherein the amount of pain killing agent in the device is below the daily unit dose for systemic treatment or daily unit dose for topical treatment using the agent and wherein said anti-inflammatory pain killing agent is in direct contact with the wound.

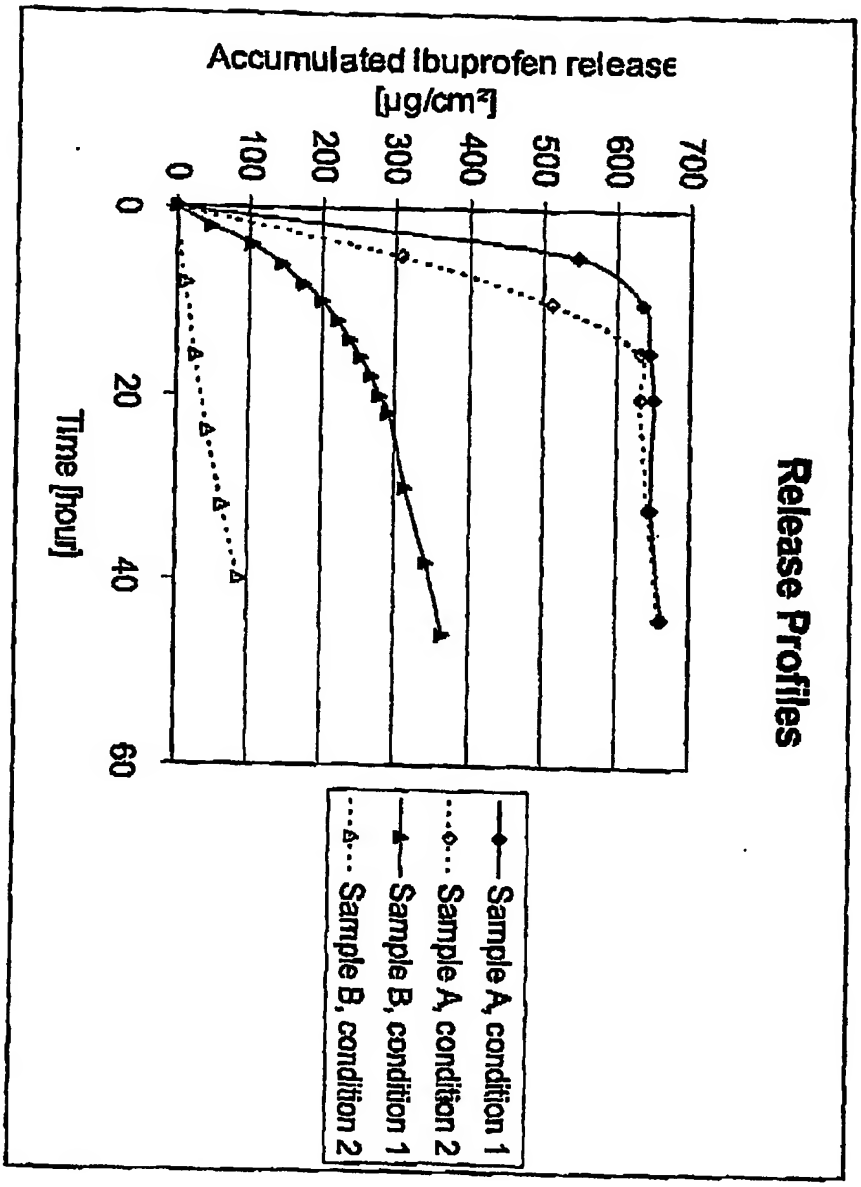

Figure 1